

**REMARKS**

Pending in the application are claims 1-51 of which claims 1, 22, 33, 42, 47, and 51 are independent. Claims 1-51 have been rejected. The following comments address all stated grounds for rejection and place the presently pending claims, as identified above, in condition for allowance.

**Claim Rejections – 35 U.S.C. §112**

Claim 31 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has indicated some confusion as to what period of time is being claimed. Claim 31 states that “the electronic record logs the duration of a time period during which the user records said clinical trial data.” Applicants believe this clearly indicates that the time period is the duration which the user records the clinical trial data.

**Claim Rejections - 35 U.S.C. §102**

Claims 1-32 and 51 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,362,440 (“Karidis”). Claims 33, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Straka et al; Patient Self Reporting of Compliance Does not Correspond with Electronic Monitoring: An Evaluation Using Isosorbide Dinitrite as a Model Drug (“Straka”). Applicants respectfully traverse the rejection for the following reasons.

**Summary of Patent No. 6,362,440 (“Karidis”)**

Karidis is directed to a flexibly interfaceable portable computing device that includes a display coupled to a processor, which is coupled or selectively coupled to either or both of a keyboard and a recording unit. The display and the keyboard provide a first user interface to the processor. The recording unit is superimposable with a removable markable surface. A stylus allows user marking on the markable surface. The stylus provides a stroke signal and a stroke mark. The recording unit, the markable surface, and the stylus provide a second user interface to the processor. Optionally, the display also contributes to providing the second user interface to the processor. Switching among viewing modes for the display, and synchronization of

information between the processor and a processor of the recording unit are also provided. A casing can enfold the display, the keyboard, and the recording unit to form a relatively slim profile. A portable computer system can have a display, a keyboard, and thick components enfolded and/or located within an overall thickness substantially equal to a sum of a first thickness for the display plus a second thickness for the keyboard, to present a slim profile.

### Summary of Straka

The Straka article is directed to a study which compared personal diary records with the use of a computerized vial that monitored the opening and closing of the vial.

### Claims 1, 22, and 51

Karidis fails to disclose each and every element of claims 1, 22, and 51. Specifically Karidis fails to disclose a paper diary as set forth in claims 1, 22, and 51. This is an important element of the present invention in that electronic instrumentation is added to the paper diary to record the use of the paper diary. Indeed one of the benefits of the present invention is that the electronic instrumentation is unobtrusive so that a user records data in the paper diary without necessarily being aware the usage is being monitored. That is, the electronic instrumentation doesn't interfere with the normal usage of the paper diary.

Karidis makes no disclosure whatsoever of a paper diary and is quite obviously a portable computer with a recording device. Indeed, a user of the device of Karidis would be very aware of the device being a portable computer (it has a display) and is imputing information into the portable computer and not a paper diary. Thus there is no disclosure of a paper diary in Karidis. Also, the portable computer of Karidis does not generate a record of the use of the paper diary. It monitors the use of the device itself. Thus Karidis also fails to disclose electronic instrumentation for generating an electronic record of diary use. As such Karidis fails to disclose each and every element of claims 1, 22, and 51.

In light of the foregoing arguments, Applicants respectfully submit that claims 1, 22 and 51 are patentable over Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 1, 22, and 51 under 35 U.S.C. §102, and pass the claim to allowance.

Claims 2-21 and 23-32

Claims 2-21 depend from claim 1 and claims 23-32 depend from claim 22. As such, claims 2-21 and 23-32 incorporate each and every element of claims 1 and 22 respectively. As set forth above, Karidis fails to disclose each and every element of claims 1 and 22. Therefore Karidis fails to disclose each and every element of claims 2-21 and 23-32.

In regard to claims 4-7, 10-11 and 13, the Examiner has asserted that the use of sensors to detect specific events such as opening or closing is non-functional descriptive data. This is simply not true. The subject matter of claims 4-7, 10-11, and 13 clearly set forth how the instrumented diary operates to determine use of the diary. That is, the electronic instrumentation senses when the diary is opened and closed to determine usage of the diary. This is clearly functional language.

In light of the foregoing arguments, Applicants respectfully submit that claims 2-21 and 23-32 are patentable over Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 2-21 and 23-32 under 35 U.S.C. §102, and pass the claims to allowance.

Claim 33

Straka fails to disclose each and every element of claim 33. Specifically, Straka fails to disclose detecting an event related to data entry in a paper diary for recording data. Straka discloses monitoring the use of the vial that holds the medicine in the study. The MEMS vial in Straka only detects the opening and closing of the vial itself it does not detect the use of the paper diary. The MEMS vial cannot determine when a data entry is made in the paper diary. Using the methodology of Straka cannot detect proactive or retroactive data entry in a diary because it detects the usage of the vial not the diary. In contrast, the present invention tracks the usage of the diary and allows for the detection of such proactive or retroactive data entry. Thus Straka fails to disclose each and every element of claim 33.

In light of the foregoing arguments, Applicants respectfully submit that claim 33 is patentable over Straka. Applicants therefore request the Examiner withdraw the rejection of claim 33 under 35 U.S.C. §102, and pass the claims to allowance.

Claims 38 and 39

Claims 38 and 39 depend from claim 33. As such, claims 38 and 39 incorporate each and every element of claim 33. As set forth above, Straka fails to disclose each and every element of claim 33. Therefore Straka fails to disclose each and every element of claim 38 and 39.

In light of the foregoing arguments, Applicants respectfully submit that claims 38 and 39 are patentable over Straka. Applicants therefore request the Examiner withdraw the rejection of claims 38 and 39 under 35 U.S.C. §102, and pass the claims to allowance.

Claim Rejections - 35 U.S.C. §103

Claims 34-37, 40, and 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Straka in view of Karidis. Claims 42-50 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hyland et al: Diary Keeping in Asthma: Comparison of written and Electronic methods (“Hyland”); further in view of Karidis. Applicant respectfully traverses the rejection for the following reasons.

Summary of Hyland

The Hyland article is directed to a study which compares data entry in paper diary with data entry into a computer.

Claims 34-37, 40, and 41

Claims 34-37, 40, and 41 all depend from claim 33 and as such incorporate each and every element of claim 33. For much the same reasons as discussed in regards to the 35 USC 102 rejection, Straka fails to teach or suggest each and every element of claim 33. Specifically, Straka fails to teach or suggest detecting an event related to data entry in a paper diary for recording data. Indeed Straka would appear to teach away from the present invention. Straka teaches monitoring the use of the vial that holds the medicine in the study. The MEMS vial in Straka only detects the opening and closing of the vial itself it does not detect the use of the paper diary. The MEMS vial cannot determine when a data entry is made in the paper diary.

That is, the methodology of Straka can only detect if there is a discrepancy between the recorded usage of the vial and the diary. Straka cannot determine why there is a discrepancy. Using the methodology of Straka cannot detect proactive or retroactive data entry in a diary because it detects the usage of the vial not the diary. In contrast, the present invention tracks the usage of the diary allows for the detection of such proactive or retroactive data entry. Furthermore, Straka clearly set forth that the people being monitored were informed of what the vial did (monitor use). In contrast, one of the advantages of the present invention is that it is unobtrusive so that the diary user need not even be aware of the monitoring. Thus, Straka fails to teach or suggest each and every element of claim 33. The addition of Karidis fails to cure this deficiency. As discussed above, Karidis makes no mention whatsoever of a paper diary. As such, Karidis does not teach or suggest the recording of use of a paper diary. Thus neither Straka nor Karidis, alone or combined, teach or suggest each and every element of claim 33. As claims 34-37, 40, and 41 all depend from claim 33, neither Straka nor Karidis teach or suggest each and every element of claims 34-37, 40, and 41.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 34-37, 40, and 41 are patentable over Straka and Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 34-37, 40, and 41 under 35 U.S.C. §103, and pass the claims to allowance.

#### Claims 42 and 47

Hyland fails to teach or suggest each and every element of claims 42 and 47. Contrary to the Examiner's assertion Hyland does not teach a method for generating electronic records concerning a paper diary entry. The study of Hyland involved the participants making two separate diary entries: one paper diary and one computer diary. The electronic records of the use of the paper diary were not generated. Usage was only tracked on the computer not the paper diary. Combining the two methods of data entry (paper and computer) would have undermined the whole purpose of the study (comparing the two methods). Furthermore, as discussed above, Karidis makes no mention of a paper diary whatsoever. The device of Karidis is effectively the computer log in the Hyland study. Thus the combination of Karidis with Hyland does not cure

the deficiencies of Hyland. As such neither Hyland nor Karidis alone or in combination teach or suggest each and every element of claims 42 and 47.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 42 and 47 are patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 42 and 47 under 35 U.S.C. §103, and pass the claims to allowance.

Claims 43-46 and 48-50

Claims 43-46 depend from claim 42 and claims 48-50 depend from claim 47. As such claims 43-46 and 48-50 incorporate each and every element of claims 42 and 47 respectively. As discussed above the combination of Hyland and Karidis fails to teach or suggest each and every element of claims 42 and 47. Thus, the combination of Hyland and Karidis fails to teach or suggest each and every element of claims 43-46 and 48-50.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 43-46 and 48-50 are patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 43-46 and 48-50 under 35 U.S.C. §103, and pass the claims to allowance.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If, however, the Examiner considers that further obstacles to allowance of these claims persist, we invite a telephone call to Applicant's representative.

Dated: January 4, 2006

Respectfully submitted,

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